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Charles E. Van Horn
Finnegan, Henderson, Farabow, Garrett & Dunner. L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001-4413

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,776,944

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,776,944, which claims the human drug product FACTIVE® (gemifloxacin mesylate), methods of its preparation and compositions comprising FACTIVE®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 659 days.

Applicants also filed patent term extension applications for U.S. Patent Nos. 5,633,262 and 5,962,468 for the regulatory review period for FACTIVE®. Pursuant to 37 C.F.R. 1.740 (a)(13) Applicants informed the PTO, in their August 24, 2005 communication of the reexamination certificate issued on June 14, 2005 for 5,776,944. In that communication, Applicants also expressly elected U.S. Patent No. 5,776,944 to be extended under 35 U.S.C. 156.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 659 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 15, 2004, (69 Fed. Reg. 12160), would be 1,470 days. Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (832 days- 305 days) + 1,206 days
	=	1,470 days (4.0 years)

Since the regulatory review period began September 6, 1997, before the patent issued (July 7, 1998), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From September 6, 1997, to and including, July 7, 1998, is 305days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,470 days, would extend the patent from June 15, 2015 to June 24, 2019, which is beyond the 14-year limit (the approval date is April 4, 2003, thus the 14 year limit is April 4, 2017). The period of extension is thus limited to 659 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, June 15, 2015, to and including April 4, 2017, or 659 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,776,944
Granted:	July 7, 1998
Original Expiration Date[1]:	June 15, 2015
Applicant:	Hong et al.
Owner of Record:	LG Life Sciences, Ltd.
Title:	7-(4-AMINOMETHYL-3-METHYLOXYIMINOPYRROLIDIN-1-YL)-1-CYCLOPROPYL-6-FLUORO-4-OXO-1,4-DIHYDRO-1,8-NAPHTHYRIDINE-3-CARBOXYLIC ACID AND THE PROCESS FOR THE PREPARATION THEREOF
Product Trade Name:	FACTIVE® (gemifloxacin mesylate)
Term Extended:	659 days
Expiration Date of Extension:	April 4, 2017

[1]Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext.
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Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755.

Kery A. Fries

Kery Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy

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Attention: Claudia Grillo

RE: FACTIVE® (gemifloxacin mesylate
FDA Docket No.: 2003E-0448